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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,734	08/10/2001	Claude P. Selitrennikoff	MYCOLOGX-06279	7203

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/927,734

**Applicant(s)**

SELITRENNIKOFF ET AL.

**Examiner**

Francisco C Prats

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-21 is/are rejected.
- 7) ☒ Claim(s) 1-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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#### **DETAILED ACTION**

Claims 1-21 are presented for examination.

#### ***Claim Objections***

Claims 1-21 are objected to because of the following informalities:

At line 18 of claim 1 (line 20 of page 44), and at line 25 of claim 6 (line 8 of page 46), the term

-- 2-nitro-thiobenzoate --

has been misspelled as "2-nitro-thiobezoate" (note the missing letter "n" in the recitation -- thiobenzoate --).

Claims 1 and 6 and their dependents are therefore objected to. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, although applicant provides an assay for identifying the compounds recited in claims 13-21, applicant does not provide the structure of a single compound which is identified by the assay. Moreover, applicant's disclosure as filed does not provide any examples of the compounds presently claimed. In view of the lack of examples and structural details of the compounds recited in the claims, a holding of lack of written description is clearly required.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As discussed above, the specification as filed fails to provide any details with respect to the structures of the compounds recited in claims 13-21. In view of the lack of disclosure of the structures of the claimed compounds, the skilled artisan would have to undertake an essentially blind

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trial and error process to determine how to make the compounds recited in the claims. Clearly, such a blind unguided process, with no clear disclosure in the specification of the likelihood of success, amounts to undue experimentation. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* such a product. A holding of non-enablement is clearly required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 15 are indefinite because those claims require the candidate compound to be "present in" an extract, or an HPLC fraction of an extract. This is confusing because it is not clear whether the compositions of claims 14 and 15 are in fact the actual extracts or extract fractions, or whether the candidate compound was obtained from those extracts or extract fractions.

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Claims 19-21 are indefinite because of the recitations "mild toxicity" in claim 19 and "limited toxicity" in claim 21. It is not clear what degree of toxicity is encompassed by the recitations "mild" and "limited," and what degree of toxicity is not encompassed by those terms. Because the terms fail to clearly set the metes and bounds of the claimed subject matter, claim 19 and its dependents must be considered indefinite.

Note further that claim 21 recites "said limited toxicity" whereas, as pointed out above, claim 19 recites "mild" toxicity, not "limited" toxicity. Thus, claims 19 and 21 are also not consistent in this regard.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchand et al (Eur. J. Biochem. 184:455-464 (1989)).

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Marchand discloses that the trypanocidal drug, suramin, inhibits phosphoglucose isomerase. See abstract. Because the reference discloses that the compound has one of the identifying properties of the claimed compositions, the ability to inhibit phosphoglucose isomerase, a holding of anticipation is clearly required.

Claims 13-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Moigne (WO 98/10656, English language equivalent U.S. Pat. 6,346,252) or Moore et al (U.S. Pat. 5,945,315). Each of Moigne (algal extract, see abstract) and Moore (cyanobacterial extract, see column 2, lines 1-10) disclose antifungal extracts obtained from the claimed biological sources. Because the references disclose that the prior art compositions have the identifying properties of the claimed compositions, antifungal activity, a holding of anticipation is clearly required.


No claims are allowed. However, claims 1-12 are free of the prior art and would be allowable if amended to overcome the objections set forth herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP